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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,786

09/28/2005

Kang Ting

38586-327005

9987

44955 7590 01/09/2007
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EXAMINER

SCHNIZER, RICHARD A

ART UNIT

PAPER NUMBER

1635

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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31 DAYS

01/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/527,786

Applicant(s)

TING, KANG

Examiner

Richard Schnizer, Ph. D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1, 3, 6, and 7, partially, drawn to methods of modulating calvarial osteoblast differentiation and mineralization by increasing the expression or activity of Nell-1 by transfecting a cell with an exogenous nucleic acid expressing Nell-1.

Group 2, claim(s) 1, 3, 6, and 7, partially, drawn to methods of modulating calvarial osteoblast differentiation and mineralization by increasing the activity of Nell-1 by delivering to a cell an exogenous Nell-1 protein.

Group 3, claim(s) 1, 2, 4, and 5, partially, drawn to methods of modulating calvarial osteoblast differentiation and mineralization by decreasing Nell-1 expression or activity by use of anti-Nell-1 antisense, ribozyme, or RNAi.

Group 4, claim(s) 1, 2, 4, and 5, partially, drawn to methods of modulating calvarial osteoblast differentiation and mineralization by decreasing Nell-1 expression or activity by use of Nell-1-specific catalytic DNA.

Group 5, claim(s) 1, 2, 4, and 5, partially, drawn to methods of modulating calvarial osteoblast differentiation and mineralization by decreasing Nell-1 expression or activity by use of anti-Nell-1 intrabodies.

Group 6, claim(s) 1, 2, 4, and 5, partially, drawn to methods of modulating calvarial osteoblast differentiation and mineralization by decreasing Nell-1 expression or activity by knocking out Nell-1 in target cells.

Group 7, claims 8-12 in part, 13-17 in full, and 20-22 in part, drawn to methods of screening for modulators of osteoblast differentiation by contacting a human test cell comprising a Nell-1 gene with a test agent and detecting a change in Nell-1 mRNA expression.

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Group 8, claims 8-12 in part, 18 and 19 in full, and 20-22 in part, drawn to methods of screening for modulators of osteoblast differentiation by contacting a human test cell comprising a Nell-1 gene with a test agent and detecting a change in Nell-1 mRNA expression.

Group 9, claims 23 and 25, partially, drawn to methods of altering Nell-1 expression by increasing expression or activity of Msx2.

Group 10, claims 23 and 24, partially, drawn to methods of altering Nell-1 expression by increasing expression or activity of Cbfa1

Group 11, claim 23, partially, drawn to methods of altering Nell-1 expression by decreasing expression or activity of Msx2.

Group 12, claim 23, partially, drawn to methods of altering Nell-1 expression by decreasing expression or activity of Cbfa1

Group 13, claims 26-35 and 38-40 drawn to methods of screening for an agent that modulates Nell-1 expression or activity by contacting a human test cell that contains a Cbfa1 and/or a Msx2 gene with a test agent and detecting a change in Cbfa1 and or Msx2 mRNA in said test cell.

Group 14, claims 26-30 and 36-40 drawn to methods of screening for an agent that modulates Nell-1 expression or activity by contacting a human test cell that contains a Cbfa1 and/or a Msx2 gene with a test agent and detecting a change in Cbfa1 and or Msx2 protein in said test cell.

Group 15, claim 41, partially, drawn to a pharmaceutical composition comprising a nucleic acid encoding a Nell-1 protein.

Group 16, claim 41, partially, drawn to a pharmaceutical composition comprising a Nell-1 protein.

Group 17, claim 41, partially, drawn to a pharmaceutical composition comprising an agent that alters expression or activity of a Nell-1 protein.

The inventions listed as Groups 1-17 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Ting et al (WO 01/24821) disclosed methods of treating osteoporosis in a human by increasing the concentration of Nell-1 gene product in an osteogenic cell by transfecting the cell with a Nell-1 expression vector. See e.g. page 4, lines 16-28; page 6, lines 24-28. Ting also taught methods of screening for assays that modulate Nell-1 expression, see page 11, lines 9-27. Thus there is no special technical feature linking the claimed inventions.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, J. Douglas Schultz, can be reached at (571) 272-0763. The official central

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fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

A handwritten signature in black ink, appearing to read 'RSchnizer', with a long horizontal flourish extending to the right.

Richard Schnizer, Ph.D.
Primary Examiner
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